

# **COVER PAGE**

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**Official study title:**

Computational Design, Fabrication, and Evaluation of  
Optimized Patient-Specific Transtibial Prosthetic Sockets

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**Principal investigator:**

Prof. Hugh Herr

**Sponsor:**

NIH

**Participating sites:**

Massachusetts Institute of Technology (MIT), Cambridge,  
MA, USA

McGovern Institute for Brain Research, MIT, Cambridge,  
MA, USA

## **CONSENT TO PARTICIPATE IN NON-BIOMEDICAL RESEARCH**

### **3D Printed Prosthetic Socket for Transtibial Amputees**

You are asked to participate in a research study conducted by Dr. Hugh Herr, Dr. Kevin Moerman, Dr. Dana Solav, and Mr. Bryan Ranger, all from the Biomechatronics Group, MIT Media Laboratory at the Massachusetts Institute of Technology (M.I.T.). You were selected as a possible participant in this study because you are a healthy transtibial adult amputee, capable of normal walking using prosthetic devices. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this study is completely VOLUNTARY and you are free to choose whether to be in it or not. If you choose to participate in this study, you may subsequently withdraw from it at any time without penalty or consequences of any kind by notifying the Principal Investigator, Dr. Hugh Herr ([hherr@media.mit.edu](mailto:hherr@media.mit.edu)). If you choose not to participate, that will not affect your relationship with M.I.T. or your right to health care or other services to which you are otherwise entitled or will not cause you to lose your research compensation.

- **PURPOSE OF THE STUDY**

The overall goal of this study is to clinically evaluate a new framework for prosthetic socket design. The framework enables the design of prosthetic sockets based on patient measurements and computer simulations. By using this framework comfortable socket can be designed and fabricated in a faster and more cost-effective way compared with conventional processes.

- **PROCEDURES**

Your involvement in this study consists of two sessions:

- 1) Data collection
- 2) Socket evaluation

In the first session data is collected, such as your residual limb shape and tissue stiffness. This data is then used by the researchers to create a computer model of the residual limb which is required for the computer simulation based design of the novel prosthetic sockets. Next you will be invited for a second session where these novel sockets are evaluated and compared to your conventional sockets (based on measurements for a standing and walking exercise you will take part in).

#### Session 1: Data collection

The main purpose of this session is to record your residual limb shape and tissue stiffness (mechanical properties). Tissue shape is recorded using scanning techniques such as MRI (Magnetic Resonance Imaging) photography, 3D scanning, and ultrasound. Tissue mechanical properties are measured using stiffness measurement devices which include

indentors. Non-painful gentle indentations will be used at selected anatomical locations (e.g. the calf muscle).

The MRI scans are conducted at the McGovern Institute for Brain Research at MIT (N46-1171) and the MRI sessions take about 1 hour (individual scans take about 5-10 minutes but multiple scans may be required). All other data collections and the mechanical property investigations take place at the Biomechanics Group of MIT Media Lab (E14-274) and also take approximately 1 hour. The indentations may also be conducted during MRI inside the MRI scanner.

During the data collection phase basic morphological data (such as height, weight, limb length and circumference) will also be recorded.

In total, session 1 requires approximately 3 hours (e.g. 1 hour of image data collection, 1 hour of mechanical property investigation, and 1 hour for other data collections and time required to walk from the Media Lab to the McGovern Institute).

You may ask the researchers to rest (e.g. between scans) or to terminate any of the tests at any time.

### Session 2: Socket evaluation

During a second session, the sockets (designed based on the image and mechanical property data) will be evaluated at the MIT Media Lab's Biomechanics department. In this session we will evaluate the novel prosthetic sockets and compare them against your conventional prosthetic sockets. The comparison is based on a standing and a walking exercise and on measurements of skin pressure, energy consumption and motion data. Pressure is an indication of tissue load and discomfort, energy consumption tells us if the socket leads to an increased or decreased amount of energy used for walking, and the motion data informs us of any walking pattern changes due to the sockets.

To measure skin pressure a set of this and flexible sensors are placed on the skin surface to measure pressure (Figure 1A). After sensor placement, a liner (either your own liner in the case of your conventional socket, or a different liner in the case of the novel socket) is rolled over the skin and sensors. Next the sockets to be tested are donned on. For the novel sockets a commercially available sleeve is used for suspension, and the socket is first attached to your conventional foot-ankle system (Figure 1B), and alignment is optimized by a certified prosthetist involved in this study: Bob Emerson (A Step Ahead Prosthetics). Once you have been fitted with the sockets the standing and walking exercises are conducted. For the walking exercise, skin pressure, energy use, and motion data are recorded. To assess energy consumption, you will be equipped with a breath-by-breath portable telemetric mask system (Figure 1C). You will also be equipped with 46 reflective markers on selected anatomical sites allowing for motion analysis.

For the standing evaluation you will be asked to stand still in an upright position for 5 minutes while skin pressure and resting energy consumption are recorded.

For the walking evaluation you will be asked to walk at 1.4 m/s for 10 minutes on an instrumented treadmill (Figure 1C) while ground reaction forces, motion data, and energy consumption data are recorded. The treadmill is equipped with side bars in case you need them for support, and two researchers, the dermatologist and the prosthetist will be present at all times while you perform the walking exercise.

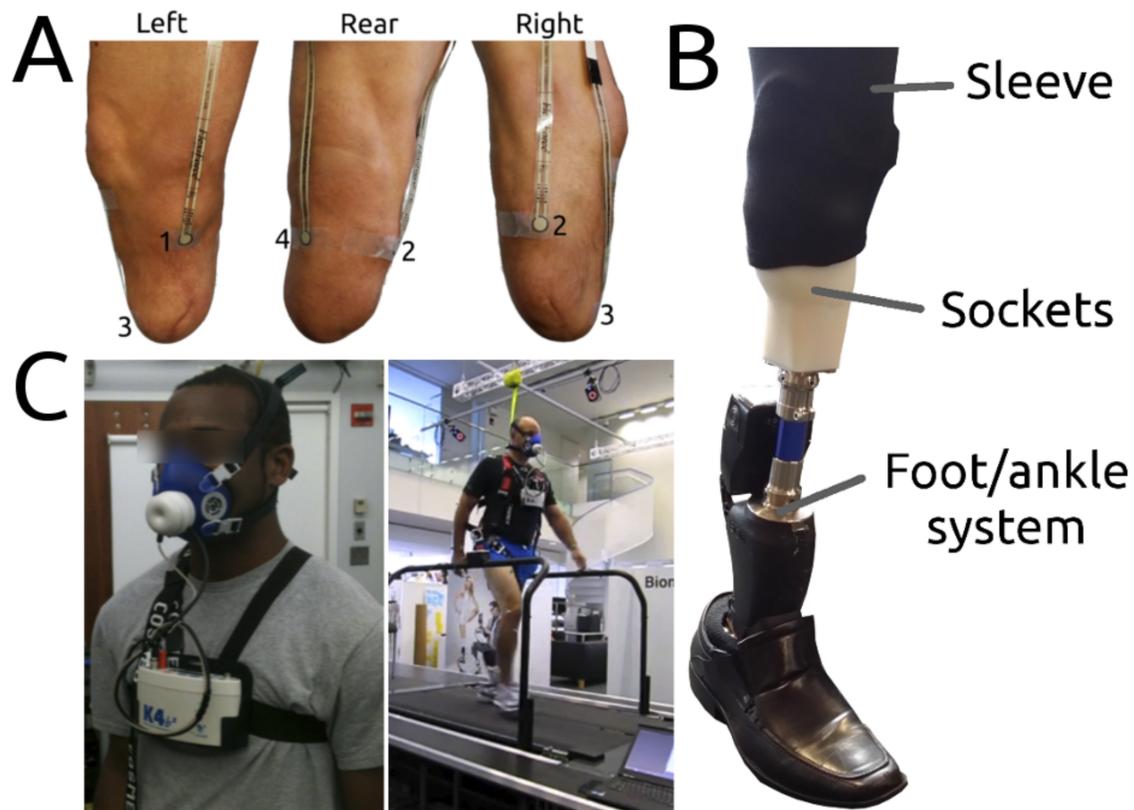
After the standing and walking exercises you will be requested to take off the socket and liner to expose their residual limb skin surface. A dermatologist involved in

the study (Dr. Tan) will then inspect your skin tissue for any signs of skin irritation (e.g. redness). The dermatologist will also talk to you and ask general questions about comfort. The dermatologist will also help you fill out a Socket Evaluation Questionnaire (SEQ). Questions will also relate to points where skin pressure measurements are made, thus enabling direct comparison of local comfort assessment to pressure findings.

Throughout the study, you will be videotaped and photographed to document the effect of the prosthesis on walking.

The socket evaluation session (instrumentation and set-up, performing the walking and standing evaluations, and filling out the SEQ) will take approximately 4 hours to complete.

You may ask the researchers to rest (e.g. during the walking exercise) or to terminate the tests at any time. At any time, you may address any concerns about comfort to the researchers, the dermatologist, and the prosthetist.



*Figure 1: Examples of: A) load sensor placement, B) The socket, sleeve, foot/ankle system, C) the set-up for the walking exercise and metabolic analysis*

- **POTENTIAL RISKS AND DISCOMFORTS**

- As with any prosthetic for walking, there is a small risk of falling during the trials. This will be minimized in the second session by having parallel bars. If needed, a safety harness attached to the ceiling can be used. In the third and fourth sessions, although there are no parallel bars and safety harness for you, two assistants will walk on each side of you, if you need it or request it.
- If you become too fatigued, or if you wish to stop for any reason, you may ask to rest or stop the study at any time.
- As with any prosthetic device, you may feel physical discomfort from wearing the prosthesis. You can address any of the researchers, the dermatologist and the prosthetist at any time during the proceedings about any concerns you have.
- Attaching sensors and reflective markers to your skin uses adhesive tape. There is a small risk of discomfort or irritation resulting from the application and removal this tape.
- The mask, used for the metabolic analysis, may feel uncomfortable. You may ask to remove the mask, rest or stop at any time.
- Confidential information about you will be collected as part of this study. Although significant efforts are made to guard your confidential information, as described in the “Privacy and Confidentiality” section below, there exists a risk that your confidential information may be disclosed.
- This device is investigational and there may be risks and side effects that are currently unknown and/or unanticipated.

- **POTENTIAL BENEFITS**

There are no immediate benefits for participating in this study. The prosthetic sockets produced will be prototypes and would not be immediately available.

- **ALTERNATIVES TO PARTICIPATION**

The alternative to participating in this study is to continue with your regular treatment under the direction of your primary care physician.

- **PAYMENT FOR PARTICIPATION**

You will be paid \$10/hr for your involvement in the experiment.

- **POSSIBLE COMMERCIAL PRODUCTS**

The prosthetic socket may become a commercial prosthetic device for below-knee amputees. The methodologies used to acquire the 3D data may also be commercialized.

- **FINANCIAL OBLIGATION**

Neither you nor your insurance company will be billed for your participation in this research.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research participant are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research will be disclosed to others without your written permission, except: if necessary to protect your rights or welfare, or if required by law.

Representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research.

Authorized representatives of the Food and Drug Administration (FDA) and Department of Veterans Affairs may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs or videos of you will be used for educational purposes, your identity will be protected or disguised. The videotapes and photos will be under the control of the MIT Media Laboratory's Biomechatronics Group. After the results are published, a copy of the photos and videos will be kept on file in the laboratory for future reference. You can ask to have the videos and photos deleted after the study is completed.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any side effects or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Hugh Herr, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will still receive your pre agreed compensation per hour of participation to compensate for your time, effort and travel expenses.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please contact Hugh Herr at (617) 314-3661 or at Building E14, Room 374L, 75 Amherst Street, Cambridge, MA.

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

**SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE**

I have read (or someone has read to me) and understood the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I have been given a copy of this form.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Name of Legal Representative (if applicable)

\_\_\_\_\_  
Signature of Subject or Legal Representative

\_\_\_\_\_  
Date

**SIGNATURE OF INVESTIGATOR**

I have explained the research to the subject or his/her legal representative and answered all of his/her questions. I believe that he/she understands the information described in this document. In my judgment the subject is voluntarily and knowingly giving free, informed consent and possesses the legal capacity to give informed consent to participate in this research study.

\_\_\_\_\_  
Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date